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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/483,588	01/14/00	PRESTA	L P1726R1

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HM12/0925

EXAMINER	
SAUNDERS, D	
ART UNIT	PAPER NUMBER
1644	11

DATE MAILED:

09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademark

Office Action Summary

Application No.

483,588

Applicant(s)

PRESTA

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/16/01
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-49 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☐ Claim(s) is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☒ Claim(s) 1-49 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Applicant's response (Paper 9) to the restriction requirement mailed 6/20/01 (Paper 8) is acknowledged. Upon further consideration, the examiner considers further restriction necessary. The examiner apologizes for any delay or inconvenience incurred by this further restriction.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, 23-30 and 36-37, drawn to engineered antibodies with increased ADCC activity or binding affinity for an Fc gamma receptor, classified in class 424, subclass 133.1 and class 530, subclass 387.3.
- II. Claims 14-22, drawn to engineered antibodies with decreased binding affinity for an Fc gamma receptor, classified in class 424, subclass 133.1 and class 530, subclass 387.3.
- III. Claims 31-33, drawn to polypeptides with reduced binding affinity for an FcRn, classified in class 530, subclass 387.1.
- IV. Claims 31 and 34-35, drawn to polypeptides with increased binding affinity for an FcRn, classified in class 530, subclass 387.1.
- V. Claims 38-42, drawn to nucleic acids, vectors, host cells, and methods of producing a polypeptide with increased ADCC activity or binding affinity for an Fc gamma receptor, classified in class 435, subclass 69.6.
- VI. Claim 43, drawn to a method of treating a disorder with polypeptides with increased ADCC activity or binding affinity for an Fc gamma receptor, classified in class 424, subclass 133.1.

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VII. Claims 44-49, drawn to methods of selecting a variant Fc having altered FcR binding or altered ADCC wherein the alteration is an increase in these activities, classified in class 435, subclass 7.1+.

VIII. Claims 44-45 and 47-49, drawn to methods of selecting a variant Fc having altered FcR binding or altered ADCC wherein the alteration is a decrease in these activities, classified in class 435, subclass 7.1+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the products having increased and the products having decreased binding affinities have different properties and functions and different motivations for their production (note, the examiner considers any claim drawn to a polypeptide having increased binding affinity for one species of Fc gamma receptor and a decreased binding affinity for a second species of Fc gamma receptor as falling within Group I and not Group II). Furthermore, Fc gamma receptors and FcRn receptors have distinct functions; the motivation to make changes in binding affinities for various Fc gamma receptors appears to be related to a desire to alter ADCC activity, while the motivation to make changes in the binding affinities for FcRn receptors appears to be related to a desire to make changes in clearance rates. Therefore, the searches for the inventions of Groups I, II, III and IV would require a search for distinct products.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

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functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct because the polypeptide of Group I and the nucleic acid/vector/host cell of Group V have different physiochemical properties and have different uses.

It is further noted that the method of Group V would not be used to produce the polypeptides of Groups II, III or IV.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group I could be used in the isolation of cells bearing a particular Fc receptor, or could be used in an in vitro immunoassay in which Fc receptors are used to capture antibody reagents onto a solid phase.

It is further noted that the products of Groups II, III and IV would not be used in the method of Group VI

Inventions VII (or VIII) and I (or II) are related as process of making (screening for) and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide products of Group I (or II) could have been obtained by other methods (e.g. by screening for alterations in other effector function activities of the altered polypeptides).

The methods of Groups VII and VIII differ in that the nature and properties of the polypeptide product for which one is screening and are thus distinct.

Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

In the event that any of Groups I, II, or V-VIII are elected, the following election of species is required:

Claims 1-5, 8-16, 23, 36-46 and 48-49 are generic to a plurality of disclosed patentably distinct species comprising antibodies (or nucleic acids encoding antibodies, methods of use of the antibodies, or methods of selection of the antibodies) wherein the antibodies can have increased or decreased binding affinities for distinct receptors, such as Fc gamma RI, Fc gamma RII, and Fc gamma RIII. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of antibody (or nucleic acid encoding, or method of use, or method of selecting such) having increased or decreased binding affinity for a particular species Fc gamma receptor, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

References supplied with various disclosure statements have been lost. More particularly, no references listed in the disclosure statements received 5/8/00 and 5/15/00 (refs 1-118) can be found. Applicant is requested to supply the nonpatent literature of these statements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders whose telephone number is 703-308-3976. The examiner can normally be reached on Mon.-Fri., 8:15 am-4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703-308-3973. The fax phone numbers for a response to restrictions is 703-308-3704; use attached form.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAS
September 24, 2001

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 / 1644



RESTRICTION ELECTION FACSIMILE TRANSMISSION

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